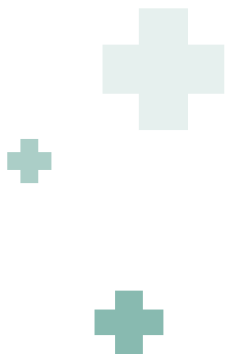




REMINGTON-DAVIS

The Evolution and Future of Clinical Research Sites



In clinical research, selecting the right site plays a pivotal role in determining clinical trials' success or failure. As this niche within the healthcare sector evolves, so does the methodology and strategies for choosing these sites. We'll discuss the changing landscape of clinical research site selection, examining the historical evolution, current trends, and the strategic considerations essential for optimal site selection.

How Modern Clinical Research Sites Emerged

Clinical research sites have come a long way from their inception. Traditionally, sites relied heavily on paper-based methods for consent, data collection, and analysis. Sharing and analyzing information across different sites was cumbersome, leading to inefficiencies in the research process. As new technology made it possible to gather data quickly and collaborate remotely, the landscape shifted.

Electronic source documents allowed for better remote management and data standardization across sites. This paved the way for the development of large site networks capable of handling complex studies like vaccine trials. The influx of private equity further accelerated this transformation, leading to the consolidation of smaller sites into expansive networks. This consolidation offered pharmaceutical companies the advantage of broader reach and standardized processes across multiple sites, streamlining operations.



Current Clinical Research Trends and Challenges

The rise of decentralized clinical trials represents one of the most significant trends in the industry today. The COVID-19 pandemic brought these trials to the forefront, shifting many trial activities from traditional clinical settings to patients' homes where they could use telemedicine and digital health technologies. Despite the advantages, decentralized clinical trials also present challenges, particularly for sites that struggle to integrate various technologies.

A 2022 SCRS Site Landscape Survey found **supporting multiple technologies for different studies is a significant challenge for 45% of sites.**

Large site networks, while offering scalability and efficiency, also introduce complexities. In these networks, a small percentage of sites often enroll the majority of the patients, highlighting a disparity in performance across the network. Additionally, errors in data collection or protocol execution can have amplified consequences, affecting multiple sites simultaneously.

In the past five years, the clinical research industry has witnessed significant merger and acquisition (M&A) activity, driven by various factors including the need for scale, the integration of new technologies, and the pursuit of diversified capabilities.

The growth of Columbus-based Centricity Research, which followed the merger of two companies in 2021 and recently expanded by acquiring a North Carolina company, is just one example. The IMA Group, backed by Centre Partners, also recently acquired Louisiana-based Clinical Trials of America, its seventh acquisition within its clinical research division since 2018, according to [PE Hub](#).

Contract research organizations (CROs) also saw an uptick in 2021 in particular, with 50 M&A deals, more than double the previous year, according to [Clinical Trials Arena](#).

Beyond CROs, the broader healthcare sector, including biotech and pharmaceutical companies, has seen a surge in M&A activity, with 65 transactions in 2023, compared to 53 the previous year, according to a [Kaufman Hall analysis](#).

The industry has also seen "mega mergers," with annual revenues exceeding \$1 billion. These deals include some of the largest health systems, such as Ascension, CommonSpiritHealth and AdventHealth, and are reshaping the healthcare landscape, with significant implications for clinical research. The consolidation of large players is often aimed at creating regional or global giants capable of dominating specific therapeutic areas or market segments.

As the landscape continues to evolve, we can expect more strategic deals that align with the industry's push toward innovation and integration.



The Role of Independent Research Sites

Independent research sites operate with a high degree of flexibility and adaptability.

These sites are often characterized by their ability to provide personalized patient care and manage complex trials that require tailored solutions. An example of such a study is a rare disease study on erythropoietic protoporphyria (EPP); Remington-Davis was selected due to its geographic location and ability to manage complex logistics.



Potential Advantages and Disadvantages

Advantages

- ✓ Strong local ties
- ✓ Personalized patient care
- ✓ More flexible and adaptable
- ✓ Fewer administrative barriers
- ✓ Potentially lower turnover

Disadvantages

- ✗ Limited resources
- ✗ Potentially higher cost
- ✗ Tech stack limitations

Independent research sites offer several advantages, including strong relationships with local healthcare providers, personalized patient engagement, and the ability to quickly adapt to study-specific needs. These sites are particularly well-suited for studies involving rare diseases or logistically complex protocols, where patient compliance and proper diagnoses are critical. They typically have fewer administrative barriers and may be more motivated to meet tight deadlines because every study has more of an impact on their overall revenue.

With these advantages come some limitations. Sponsors may need to dedicate more resources to contracting at startup as they need to engage more independent site organizations. And while not every site in a large network will operate the same and meet enrollment goals, the efficient contracting may get the study started more quickly overall. Depending on the study, these limitations can be overcome by more experienced staff that may be more common at independent sites, which tend to have lower turnover rates.

How Independent Sites Are Evolving Into Larger Networks

Research site networks are a relatively recent development in clinical research, driven by the need for more efficient patient recruitment, data standardization, and operational scalability. These networks consist of multiple clinical sites that operate under a centralized management structure. The goal is to streamline the clinical trial process by providing a consistent approach to data collection, patient care, and regulatory compliance across locations.

This allows pharmaceutical companies to negotiate a single contract that covers multiple sites, providing a more efficient pathway to initiate and conduct large-scale clinical trials.

However, the larger these networks become, the less likely they are to take on smaller, more complex studies as it becomes harder to create efficiency and scalability. Each study requires a unique approach, which is where independent sites tend to excel.



Potential Advantages and Disadvantages

Advantages

- ✓ Scalability
- ✓ Efficiency
- ✓ Consistency
- ✓ Cost-effective

Disadvantages

- ✗ Less flexibility
- ✗ Less personalization
- ✗ Mistakes are magnified
- ✗ More complexity

Site networks offer numerous advantages, particularly in terms of scale, efficiency, and data consistency. They typically have access to a larger, more geographically diverse pool of patients and a more standardized procedures for collecting data, caring for patients and reporting, which can lead to greater reliability and scalability.

Large networks benefit from economies of scale for large trials where patient recruitment and enrollment is straightforward, which can help them save money on supplies, employee training, and administrative costs. These savings can be passed on to sponsors, making networked sites a cost-effective option for large-scale trials.



Despite these advantages, networked research sites also face several challenges.

The standardized procedures and protocols that benefit data consistency may come at the cost of personalized patient care. Patients in a larger network might not receive the same level of individualized attention as they would at an independent site. This could impact patient satisfaction and, consequently, retention rates, critical toward long-term trial success.

Managing multiple sites within a network also requires more communication and coordination. The larger the network, the more challenging it is to keep all sites aligned and adherent to the same standards. This complexity can lead to delays in trial initiation, data submission, and even patient recruitment.

They may not be able to easily adapt to the unique needs of a specific trial the way smaller sites can. For instance, if a trial requires specific protocol for patient monitoring or data collection, a larger site network may not be agile enough to accommodate these needs.

Another significant disadvantage is that within a network of sites, errors or protocol deviations can have far-reaching consequences. If a mistake occurs at one site, it can easily be replicated across the entire network, leading to widespread issues that can compromise a trial's integrity. This risk is particularly high in large-scale, multi-site trials where oversight is particularly challenging. The choice between independent and networked research sites depends largely on the specific needs of a trial, including the therapeutic area, patient population, and required level of flexibility. Leveraging the strengths of both may provide the optimal path forward for conducting successful clinical trials.



Case Studies

Independent sites often have greater ability to pivot quickly when sites within a network have failed to meet recruitment goals, for instance, or when a trial is logistically complex. Here are a few examples.



CASE STUDY

Remington-Davis Brings COVID-19 Therapies to Market for Emergency Use

During the COVID-19 pandemic, Remington-Davis conducted multiple trials focusing on monoclonal antibodies and antivirals, aiming to prevent progression to severe disease in COVID-19 patients. The trials had to be set up quickly in response to the urgent public health crisis, with the need for additional clinic space, rapid patient recruitment, and compliance with stringent infection control protocols. Within 30 days, RDI established a dedicated COVID-19 research clinic, complete with IV infusion rooms and accommodations for patients.

The team used creative recruitment methods, such as placing signs near drive-thru testing centers and on college campuses, to reach a diverse patient population. The team had the flexibility to stay open seven days a week and late into the evenings.

Remington-Davis successfully enrolled 236 patients between July 2020 and February 2021, contributing to the rapid development and deployment of COVID-19 therapies. Their quick action and effective management were crucial in meeting the urgent demand for treatments.



CASE STUDY

Supporting On-Time Completion of a Three-Month Performance Study

One such study sought to validate a smart glucose meter's accuracy compared to laboratory measurements and evaluate its usability (human factors testing) for individuals with Type 1 or Type 2 diabetes. The trial required quick recruitment and efficient management to meet a tight timeline. Using a comprehensive patient database, Remington-Davis enrolled 360 patients within three months, ensuring the study remained on schedule.

The team relied on its extensive experience in regulatory processes to facilitate timely IRB submission. It was the only site in the world chosen for this study, and there was no need to use a broader network of sites. The sponsor worked directly with the owners to immediately address hurdles and delays to meet timelines.



CASE STUDY

Decentralized Study Design Keeps a Device Trial on Track

This trial involved testing migraine prevention glasses designed to block specific wavelengths of light, potentially preventing the need for other migraine medications or therapies. The study was set to start during the COVID-19 pandemic, requiring significant adjustments to the original trial design to accommodate health and safety restrictions. Remington-Davis proposed and implemented a decentralized trial model, which included telemedicine consultations and home-based delivery and collection of study devices and documents. This approach allowed the trial to continue despite the pandemic.

With an extensive patient database and efficient operational processes, RDI quickly enrolled 60 patients, ensuring the trial progressed on time. Remington-Davis demonstrated remarkable flexibility, adjusting the trial operations to meet emerging pandemic-related challenges while maintaining exceptional standards of patient care and data integrity. The trial was completed on time, despite the disruptions caused by the pandemic. RDI's ability to pivot quickly and maintain trial integrity positioned them as a leader in decentralized clinical trials. Because it was a single site, the team could focus all their energy on recruitment for a week. This resulted in 60 patients in nine days.

Effective Networked Research Sites

Networked Sites Accelerate Vaccine Trials

Networked research sites also played a critical role in conducting large-scale vaccine trials during the COVID-19 pandemic, focusing on rapid patient recruitment and standardized procedures to ensure consistent and reliable data across multiple sites.

These networks were able to quickly recruit large numbers of patients, essential for the timely development of vaccines. Using standardized protocols across sites ensured consistent data collection, improving trial results' reliability.

The ability to centrally manage operations allowed for more efficient oversight and quicker resolution of any issues that arose during the trials.

The ability of networked sites to handle large volumes of patients and maintain high data quality was instrumental in the rapid approval and distribution of COVID-19 vaccines.



A Large Network Facilitates Multi-Site Oncology Trials

This case involves a large network conducting oncology trials across multiple sites, focusing on recruiting diverse patient populations and maintaining rigorous data standards.

By operating across different geographic regions, the network was able to recruit a diverse patient population, improving the generalizability of trial results. The network's standardized data collection methods, supported by electronic data capture systems, ensured high-quality data that met regulatory requirements. The network's scale allowed for efficient use of resources, such as centralized training and bulk purchasing of trial supplies, reducing operational costs.

The network's ability to manage complex trials across sites resulted in timely, reliable data, contributing to the successful completion of several oncology trials.

Future Clinical Trial Trends and Predictions

Several key trends are shaping clinical research site selection and trial execution.

These trends reflect advancements in technology, shifts in regulatory requirements, and the growing emphasis on patient-centric approaches. Here are some of the most notable trends:



Integration of Advanced Technologies

The integration of technologies such as artificial intelligence (AI), machine learning (ML), and wearable devices is transforming clinical trials. AI and ML are being used to automate data analysis, enhance patient matching, and predict outcomes, leading to more efficient trial designs and faster decision-making.

Wearable devices and mobile health (mHealth) technologies allow for continuous data collection from participants, providing real-time insights and improving the overall quality of data collected during trials, according to [StartUs Insights](#).

Focus on Diversity and Patient-Centricity

Diversity in clinical trials is becoming increasingly important, driven by both regulatory requirements and the ethical need to ensure that study populations reflect the broader patient community. The FDA's emphasis on diversity underscores the need to include underrepresented racial and ethnic groups in clinical trials for more accurate diagnoses and treatment. Sponsors are more focused than ever on developing site-specific strategies to engage and retain diverse populations, often in partnership with community organizations.

Patient-centricity remains a dominant trend, with an emphasis on reducing the burden of participation. Tools that enhance the participant experience—such as eConsent, flexible visit schedules, and digital engagement platforms—are critical for improving recruitment and retention rates.

Emphasis on Rapid Trial Initiation and Execution

There is increasing pressure on sponsors to initiate trials quickly, sometimes before all details are fully finalized. This urgency is driven by the need to demonstrate progress to investors and stakeholders, leading to more frequent trial amendments and delays. To counteract these challenges, there is a growing focus on workflow integration and automation, which can accelerate study startup.

These trends highlight the importance of adaptability and innovation in clinical trials, providing assurance that studies are conducted efficiently and inclusively while maintaining high standards of data quality and patient care.

Strategic Recommendations for Sponsors

Based on the trends and challenges discussed, here are key takeaways for clinical research sponsors and principal investigators:



Embrace Hybrid Models for Decentralized Trials

While decentralized clinical trials offer numerous benefits, such as enhanced patient recruitment and operational efficiency, they may not be suitable for all studies. Sponsors should consider hybrid models that combine remote and in-person elements, allowing flexibility while maintaining necessary oversight and control.

Invest in Advanced Technologies

Incorporating AI, machine learning, wearable devices, and cloud computing can streamline data collection, improve patient matching, and provide real-time insights. Sponsors and investigators should prioritize investments in these technologies to enhance trial efficiency and data quality.

Prioritize Diversity and Patient-Centric Approaches

The FDA's emphasis on diversity in clinical trials emphasizes the importance of including underrepresented populations. Sponsors should develop site-specific strategies that engage local communities and ensure diverse patient representation. Additionally, implementing patient-centric tools and approaches, such as eConsent and flexible visit schedules, can improve recruitment and retention.

Diversify Your Network of Sites

For sponsors, diversifying relationships with both large site networks and independent sites is crucial for successful clinical trial execution. Large networks offer the scale and standardization needed for rapid patient recruitment and accelerated enrollment, making them ideal for large, global trials. Independent sites provide the flexibility and personalized patient care that can be critical for studies requiring specialized attention or those targeting niche populations.

Establishing formal partnerships with both types of sites now ensures that sponsors are prepared to quickly recruit patients, supplement data collection, and adapt to evolving trial needs. This balanced approach allows sponsors to leverage the strengths of both site types, ensuring efficient trial execution.

Why Choose Remington-Davis for Your Clinical Research Needs

Remington-Davis stands out as a premier independent clinical research site with over 30 years of experience and a proven track record in delivering high-quality data and patient-centric services. Located in Columbus, Ohio, Remington-Davis operates a state-of-the-art 5,000-square-foot research facility, equipped with six treatment rooms, five overnight rooms, and advanced laboratory processing capabilities.

Here are a few reasons sponsors choose us:

- **Rapid Enrollment**

Remington-Davis boasts an impressive 35% diversity rate among enrolled subjects and a 98% patient retention rate, ensuring a representative and committed patient population for your trials.

- **Efficiency**

Our site offers a 24-hour turnaround time for contracts and a one-week greenlight to the first patient, demonstrating our ability to meet tight timelines.

- **Therapeutic Expertise**

RDI excels in conducting complex drug and device studies across multiple therapeutic areas, including vaccines, endocrinology, dermatology, and respiratory medicine.

- **Patient-Centric Care**

We're known for personalized patient care, providing a comfortable and supportive environment that enhances patient retention and engagement throughout the trial.

- **Adaptability and Innovation**

From rapidly adapting to decentralized trial designs during the COVID-19 pandemic, to managing complex logistics for rare disease studies, we consistently demonstrate flexibility and innovation in trial management.

- **Low Turnover**

As an independent site, we have the ability to give incentives that are difficult to manage at large corporations, such as enrollment bonuses, flex time and more autonomy to do their jobs. In the past two years, we have only had two staff members leave, both of whom were accepted to medical school. That's less than a 5% turnover rate.

Don't wait until you're already behind your timeline for patient recruitment and enrollment.

Contact us today to learn more about how we can support your next trial.

CONTACT US NOW